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09/845,260	04/30/2001	Leonard E. Maroun	8221-006	4003

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,260	Applicant(s) MAROUN, LEONARD E.	
	Examiner Sharon L. Turner	Art Unit 1647	

-- Th MAILING DATE of this communication appears on the cov r sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-37* is/are pending in the application.

4a) Of the above claim(s) *20,21,25-27 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,22-24 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-37* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response filed 3-24-03 has been entered into the record and has been fully considered. Claims 18-37 are pending.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

In particular Applicant's should update the status of the '398 case as now abandoned.

Election/Restriction

3. Applicant's election with traverse of Group I, claims 18-19, 22-24, 28 to the extent of a soluble interfereon receptor in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the relationship of the inventions I-II and A-E are so related that the search and examination could proceed without an undue burden upon the Examiner. This is not found persuasive because the searches for the different groups are not co-

extensive in nature and require different searches and consideration of the prior art. A reference to any one element would not necessarily be a reference to any other.

Applicant's suggestion that elements A-E be designated as species has been considered. However, proper species share structure and function whereas particular elements of A-E do not apparently share structure although they do apparently share common function as interferon antagonists. Rejoinder to species would require a showing of evidence of common structure amongst the various elements. Rejoinder to species would be considered upon disclosure of such shared elements and upon the determination of allowable subject matter. Examination remains restricted to the extent of a soluble interferon receptor whether or not particular elements may actually be species rather than groups. Further it is noted that the shared elements should be directed to the elected element of a soluble interferon receptor as the initial search has been so limited.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 20-21, 25-27, and 29-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions (claims 20-21, 25, 27, 29, 31, 33 and 35-37) and species (claims 26, 32 and 34 drawn to antibody treatment and claim 30 being distinct as set forth below), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

It is noted that claim 30 recites wherein the antagonist blocks the production of interferon. This limitation is a functional recitation lacking particular structure. The

specification fails to disclose and the artisan fails to recognize that a soluble interferon receptor blocks production of interferon. Accordingly, the recitation appears to be directed to a non-elected species of the invention and has thus been withdrawn.

Traversal of such judgment by the Examiner should include supportive references or evidence that a soluble interferon receptor is effective to inhibit the production of interferon as claimed. Absent such showing the limitation fails to read on the invention elected for initial prosecution on the merits.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6. Claim 24 is objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

In particular the soluble interferon receptor, soluble interferon receptor fragment, antibody or peptide having an amino acid sequence derived from an interferon that occupies the receptor binding site but does not activate the receptor are molecules that

lack common structure as claimed and thus the recitations constitute an improper Markush.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18-19, 22-24, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for effects on growth retardation, eye opening and back curvature as exemplified in Table 1 and pp. 16-21 with anti-IFN antibody treatment, does not reasonably provide enablement for treatment of all dementia or dementia associated with amyloid plaques with any interferon antagonist, derivative of an interferon antagonist or soluble interferon receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors particularly relevant in this discussion are the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The claims recite a method of treating dementia. The Merck Manual of Diagnosis and Therapy defines dementia as a structurally caused permanent or progressive decline in several dimensions of intellectual function that interferes substantially with the person's normal social or economic activity, p. 1403, in particular. The symptoms, signs and course of dementia are discussed on pages 1404-1405, including depression, paranoia and anxiety, in particular. The Merck Manual further states that dementia generally is an insidious, slowly progressive, untreatable condition, p. 1406, Prognosis, line 1. Thus dementia describes a genus of disorders caused by different underlying diseases, with different etiologies, which would not be expected to respond similarly to a single treatment.

For example, both Parkinsons Disease and Alzheimers Disease are disorders associated with dementia. Treatment for Parkinsons is generally geared toward the effective increase of dopaminergic output from neurons in the basal ganglia whereas treatments for Alzheimer's is generally geared toward the reduction in diffuse amyloid plaques or decreased amyloid synthesis. Nevertheless the art further recognizes that Down's syndrome patients exhibit Alzheimer's type pathology, see in particular Lott et al., Annals of the New York Academy of Sciences, 1982, 396:15-27. Moreover, the art recognizse that dementia associated with Down's syndrome is related to extrachromosomal copies of multiple interferon genes that create a supersensitivity to interferon, see in particular Maroun et al., J. of Theoretical Biol., 1996 July 7, 181(1):41-6 and Gerdes et al., Scandinanvian J. of Clin. & Lab. Invest., 52(3):189-92, May 1992. Such is not apparently limited to Down's syndrome but may be related in Alzheimer's

and other forms of dementia. For example alpha-interferon is induced in Alzheimer pathology but not in Parkinson's Disease, see in particular Yamada et al., Neurosci. Lttrs, Nov. 7, 1994 181(1-2):61-64 and that both Alzheimer's patients and Down's syndrome patients exhibit sensitivity to interferon alpha, see in particular Mowshowitz et al., J. of Neural Transmission, 1983, 57(1-2):121-126. Thus, while instant specification does not teach treatment of dementia in the instant model system, it does provide benefit for symptoms associated with trisomy in a mammalian model system that is considered indicative of Down's syndrome disease. In particular, the teachings are similar to that disclosed in Maroun et al., Teratology, May 1995, 51(5):329-35.

However, while the artisan recognizes that trisomy patients with Down's syndrome exhibit dementia similar to instant trisomic model system, the specification's teachings are not indicative of providing treatment for dementia as generically encompassing age-related dementia, injury related dementia, dementia of the Alzheimer type or to late dementia in Parkinson's patients. The artisan would not expect that a treatment effective for one pathology to necessarily provide for the alleviation of another. Instant specification shows that delivery of anti-interferon IgG to mothers of trisomic fetuses improved overall fetal growth, eye opening and back curvature. However, the specification provides no guidance whereby one of skill in the art can be reasonably assured that such administration is capable of treating dementia as generically claimed in either the trisomic model system or in any related or diverse form of dementia as experienced by patients. There are no assays disclosed whereby the artisan can predictably and reliably measure the effectiveness of such treatment

particularly in an embryonic animal. No guidance is given as to what doses and/or routes of administration are effective and the peptides to be administered are variable in structure. In particular it is noted that only anti-IgG was shown to be effective for fetal growth, eye opening and back curvature, yet the claims encompass any form of interferon antagonist. There are no symptoms of dementia that are specifically improved by such treatment and the treatment does not apparently provide for improved intellectual function.

The skilled artisan further recognizes the unpredictability in the art regarding conservation of peptide function based upon divergent structure, even in highly conserved families, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. Thus, while anti-interferon treatment appears suitable for providing the noted effects in embryonic fetuses, there appears to be no such correlation with other interferon antagonists including soluble interferon receptors as is instantly claimed.

Thus, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 18-19, 22-24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerdes et al., Scand. J. of Clin. & Lab. Invest., 1992 May, 52(3):189-92, Maroun et al., Teratology, 51(5):329-35, May 1995, Mitsuyama et al., Jpn J Psychiatry Neurol. 1992 Sep;46(3):741-8, Merimsky et al., Eur J Cancer. 1990;26(5):596-600, Yamada et al., Neuroscience Lttrs., 181(1-2) :61-64, 1994, Moshowitz et al., J. of Neural Transmission, 57(1-2) :121-126 and Revel et al., US 5,643,749 filed 10-24-1994.

Gerdes et al., teach that the gene coding for the alpha,beta-interferon (alpha,beta-IFN) receptor is localized to chromosome 21. Cells from patients with Down's syndrome (trisomy 21) contain an extra chromosome 21, which results in a 1.5

times increase of dosage for the genes localized to this chromosome. Trisomy 21 cells express more cell-surface alpha-IFN receptors, consistent with the increased gene dosage. Down-regulation of the alpha-IFN receptors in trisomy 21 and normal cells was studied by incubating the cells with alpha-IFN. The alpha-IFN-induced effects showed 1.6 times more internalized cell-surface alpha-IFN receptors in trisomy 21 cells compared with normal cells, but no statistically significant change in the dissociation constants, see in particular Abstract. Thus, increased alpha-IFN receptor is associated with Down's syndrome related dementia.

Maroun et al., teach mouse trisomy 16, a well-studied model for human chromosome 21 trisomy (Down's syndrome). The late stage trisomy 16 mouse fetus exhibits significant growth retardation, inappropriately opened eyes, and convex rather than concave back curvature. The interferons (alpha, beta, and gamma) have potent growth retarding activity, and sensitivity to these cytokines is controlled by genes that map to mouse chromosome 16 and human chromosome 21. In experiments designed to determine if the interferons induce or aggravate the trisomy phenotype, mice pregnant with trisomy 16 fetuses were injected with a combination of anti-alpha, -beta, and -gamma interferon IgG. This maternal anti-interferon treatment was found to provide measurable benefit to the development and growth of the trisomic fetuses with significant return-toward-normal values observed for overall fetal growth, eye opening, and back curvature.

Mitsuyama et al., teach the clinical effects of over-exposure to interferon. In particular, Mitsuyama teach interferon encephalopathy in a 78-year-old male with renal

carcinoma treated with a high dose infusion of interferon-alpha (IFN-alpha) for eight months. The patient had evidence of organic brain syndrome such as dysfunction of memory, slowing of behavior, and development of mental confusion that appeared eight months after the treatment. MRI at the time of mental confusion revealed diffuse white matter lesions. Neuropathologic findings were compatible to Binswanger's disease and Senile Dementia of Alzheimer Type (SDAT), Preexisting neurologic abnormalities including intracerebral arteriosclerosis and cerebral atrophy may incr0ease susceptibility to unacceptably severe IFN neurotoxicity, see in particular abstract.

Merimsky et al., teach interferon-related mental deterioration and behavioral changes in patients with renal cell carcinoma. Five out of 38 patients (13%) with metastatic renal cell carcinoma had mental deterioration 3 weeks to 13 months after the start of treatment with recombinant interferon alpha-C. Metastatic spread to the brain, paraneoplastic effect of the tumor on the central nervous system and other causes of dementia were excluded. Computed tomography of the brain in these patients was normal and the width of the cerebral sulci and ventricles did not correlate with the severity of dementia. Specific patterns of atrophy were not seen. General deterioration, assessed by the change in Karnofsky performance status, was associated with dementia. The dementia may have been caused by a neurotoxic effect of interferon, see in particular abstract.

Yamada et al., teach increased alpha-interferon expression in reactive microglia of Alzheimer brain, a disorder associated with amyloid plaque pathology.

Moshowitz et al., teach Alzheimer's and Down's syndrome fibroblasts that exhibit enhanced sensitivities to interferon.

Revel et al., teach soluble interferon receptors and their use for inhibiting the activity of interferon alpha and beta including wherein patients have an excess of interferon, see in particular column 5, lines 32-46.

Accordingly, the literature recognizes interferon dys-regulation in Down's syndrome and Alzheimer's patients resultant from over-expression of interferon and/or interferon receptors. Moreover the literature recognizes the effectiveness of interferon inhibition using anti-interferon for the mediation of the pathogenic traits of Down's syndrome disease. The literature further recognizes that interferon over-expression causes dementia and that blockage of interferon via mediation with soluble interferon receptor can be used to treat patients where over-expression of interferon is pathogenic and causes disease. Thus, the artisan based upon the cumulative reference teachings would be motivated to treat dementia resulting from interferon mediated effects (such as in Down's syndrome and Alzheimer's disease) via administration of soluble interferon antagonists to block interferon and interferon signaling mediated via interferon binding at the receptor. One of skill in the art would have expected beneficial effects utilizing such treatment based upon the references cumulative teachings of interferon antagonism via the soluble receptor and the recognition that interferon over-expression is associated with and causative of dementia in vivo including to dementia related to Down's syndrome disease that is associated with interferon dys-regulation via over-

expression of interferon receptors. Thus, the cumulative reference teachings render the invention obvious to the skilled artisan.

These rejections are not in conflict with the enablement rejection above. As stated in Ex parte Dash, 27 UPQ2d 1481 (BdPatApp&Int, 1993("[w]e are not unaware that we are sustaining rejections under lack of enablement based on reasons which also apply to the prior art" and "[I]f appellants overcome the lack of enablement of their claims, they will necessarily overcome the lack of enablement of the references". All of the elements of the claimed invention were in the prior art. Further, the instant specification provides neither an element of predictability that was lacking from the prior art or the disclosure of unexpected results.

We recognize that In order for a reference to be anticipatory, it must be enabling. See In re Le Grice, 301 F. 2d 929,936, 133 USPQ 365, 371 (CCPA 1962) ("[B]efore any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention."), In re Donohue, 766 F.2d 531, 533, 226 USPQ 619,621 (Fed. Cir. 1985) (reaffirming La Grice; but In re Hafner, 410F.,2d 1403, 1405, 161 USPQ 783, 785 (CCPA 1969) (finding that a disclosure that fails to teach how to use a disclosed compound, while it may serve as an anticipatory reference under 35 USC 102 may fail to support the claimed invention as required by 35 USC 112, first paragraph; In re Schoenwald, 964 F.2d 1122, 1123-24, 22 USPQ2d 1671, 1673, (Fed. Cir. 1992) (following the reasoning of In re Hafner, In re Lukach, 442 F.2d 967, 970, 169 USPQ 795, 797 (CCPA 1971) (noting that "there

are... apparent anomalies between the requirements for claim-anticipating disclosures and claim-supporting disclosures"). In circumstances such as this, however, where the specification does not appear to add anything not taught by the prior art, the examiner may not have sufficient evidence to determine which rejection is more appropriate, i.e., the art rejection or the enablement rejection. If the specification is enabling, so is the prior art reference, and vice versa.

In this regard, the statements of the Court of Claims and Patent Appeals in In re Krauch, 56 F.2d 290, 12 USPQ 257 (CCPA 1932), are enlightening. In that case, the Commissioner urged, and the CCPA agreed, that Krauch's claims were unpatentable on the basis of alternate theories. The court noted that it did not have to choose between the two alternative theories as the result was the same no matter which theory was accepted-appellants were not entitled to allowance of the appealed claims. See id. at 291-92. The reasoning of Krauch is germane to the situation where the teachings of the specification appear to be commensurate with the disclosure of a previously published reference. If the specification is enabling, so to is the reference, and the claims may be unpatentable over the teachings of that reference. If the reference is not enabling, neither is the specification, and the claims may again be unpatentable. The Examiner need not choose based on the limited evidence the rejection that is the more correct one, as the result is the same in either instance-the claims are unpatentable. It is thus proper for the Examiner to make the superficially inconsistent art and enablement rejections, and place the burden on applicant to distinguish his or her specification from

the prior art and to point out how the specification goes beyond and elaborates upon what is taught by the previously published reference(s).

The instant case appears to fall squarely within the bounds of the above analysis and thus both 35 USC 112, first paragraph and 35 USC 103 rejections are set forth herein. It is noted that the Maroun et al., Teratology, 51(5):329-35, May 1995 reference is in direct correlation with the teachings of the specification that supposedly provide for enablement of instant claims. Thus, the teachings of the specification are apparently the same as that of the prior art. Accordingly, the facts are similar to that as noted in Ex parte Dash and In re Krauch above. All of the elements of the claimed invention were in the prior art. Further, the instant specification provides neither an element of predictability that was lacking from the prior art nor the disclosure of unexpected results. If the specification is enabling, so to is the reference, and the claims may be unpatentable over the teachings of that reference. If the reference is not enabling, neither is the specification, and the claims may again be unpatentable.

Nevertheless it is further noted that the additional references serve to render parts of the invention obvious to the artisan. Even without the Maroun teachings, the artisan recognized that interferon over-expression and signaling at the receptor causes interferon related dementia in vivo. Moreover, the artisan has already recognized that a suitable treatment for such over-expression is mediated via administration of soluble interferon receptor. Thus, in the instance where the dementia is recognized to be associated with over-expression of interferon, both motivation and enablement is apparently provided for the practice of the claim prior to the filing of instant application.

However, the scope of this teaching is not in full breadth of the invention claimed. Thus, the enablement is expressed as a scope of enablement rejection and the invention is obvious as to those teachings that recognize interferon-related dementia such as in Down's syndrome patients and in Alzheimer's disease.

Status of Claims

11. No claims are allowed.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
June 30, 2003